Opening Statement of Chairman Walden Subcommittee on Health Hearing on "Examining Patient Access to Investigational Drugs" October 3, 2017

(As prepared for delivery)

Today, our Health Subcommittee is reviewing an important and often emotional topic – patient access to experimental drugs for our family members, friends, and other loved ones battling serious or immediately life-threatening illnesses.

Having lost close family members in such circumstances, I understand the passion people have for finding a life-saving cure.

Previous barriers to investigational drugs led to a nationwide movement, resulting in the establishment of the Food and Drug Administration's expanded access program. Commonly referred to as compassionate use, this 1980's-era process has helped patients who do not meet the guidelines of clinical trial participation receive experimental access to unapproved drugs. The individual's physician and the drug developer must agree the potential benefits outweigh any patient safety concerns with the FDA facilitating the process. According to the non-partisan Government Accountability Office, 99 percent of the nearly 5,800 applications were approved from 2012 through 2015.

However, there is ongoing concern that some patients may not be allowed to access investigational drugs even after exhausting all other treatment options. We must examine whether there are regulatory, legal, or commercial barriers to patient access for experimental drugs.

This has led some advocates to promote a nationwide grassroots movement for state "Right to Try" laws. To date, 37 states have enacted such laws, according to the National Conference of State Legislatures, including my home state of Oregon. Many patients, like Navy veteran Matt Bellina, here with us today, have moving stories to tell. And they deserve a voice in this complex discussion.

Ultimately, this issue is about fairness. As a representative body, our responsibility is to strike the delicate balance of individual liberty, and patient safety in public policy.

For many on this committee, today marks your first formal exposure to patient access to investigational drugs. Today is an opportunity for all of us to learn more.

Thank you, Mr. Chairman, for holding this hearing. And thank you to our four panels of witnesses, I appreciate you taking the time to be with us today. I yield the balance of my time.